UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DOLISKA HANRAHAN, ROBERT HANRAHAN Plaintiffs,	))))	
vs.	)	Case No. 4:04CV01255 ERW
WYETH, INC., et al.,	)))	
Defendants.	)	

MEMORANDUM AND ORDER

This matter comes before the Court upon Defendants' Motion for Summary Judgment [ECF No. 60] and Defendants' Motion to Exclude Testimony of Plaintiffs' Experts [ECF No. 66].

I. BACKGROUND FACTS[1]

Plaintiffs Doliska Hanrahan and Robert Hanrahan[2] filed a complaint, alleging personal injury caused by Defendants' prescription hormone replacement therapy (HRT).

HRT consists of pharmaceutical products comprised of estrogen and progestin, and is prescribed to treat symptoms of menopause. After their ovaries stop producing estrogen, some

[1]The Court's recitation of facts comes from those shown to be undisputed by the parties' responses to allegations contained in the amended Complaint, Defendants' Statement of Uncontroverted Material Facts and Plaintiffs' Statement of Material Facts, and from unrefuted exhibits in the record [ECF Nos. 27, 30, 31, 61, 74]. Facts regarding the history of HRT, the Defendants' roles in that history, and the information available concerning HRT and HRT side effects additionally can be found in the Eighth Circuit's opinion concerning one of the individual "bellwether" trials conducted by the MDL court, *In re Prempro Prod. Liab. Litig.*, 586 F.3d 547 (8th Cir. 2009).

[2]The record indicates that Plaintiff Robert Hanrahan is now deceased.

women develop moderate to severe menopausal symptoms, including episodes of heat and sweating referred to as “hot flashes,” and vaginal atrophy.

Premarin and Prempro are prescription products containing conjugated equine estrogen that have been approved by the FDA to treat menopausal symptoms and to prevent osteoporosis. Provera is a prescription product containing medroxyprogesterone acetate (“MPA”) that has been approved by the FDA to reduce the incidence of endometrial cancer in postmenopausal women who have not undergone a hysterectomy and are receiving conjugated estrogen. Prior to 1995, Wyeth began developing a combination of estrogen and progestin. Prempro and Premphase are prescription products containing this combination.

Defendants Pfizer, Inc. subsidiary Wyeth, LLC f/k/a Wyeth d/b/a Wyeth, Inc., and Wyeth Pharmaceuticals, Inc. (collectively referred to as “Wyeth”) introduced Premarin in 1942. Defendant Upjohn Company launched Provera in 1959. By the 1970s, studies revealed a link between estrogen replacement drugs and endometrial cancer, and the FDA instructed Wyeth to change Premarin’s label to warn consumers of the risk of endometrial cancer in 1975. After subsequent research indicated that prescribing progestin in combination with estrogen reduced the cancer risk this combination hormone therapy became the standard of care. In 1994, Wyeth introduced Prempro, the first pharmaceutical combining estrogen and progestin in a single tablet.

During the relevant time, Wyeth researched, tested, manufactured, marketed, distributed, and sold Premarin, Prempro, and Premphase. Wyeth also manufactured, distributed, marketed and sold Cycrin, a form of MPA. A predecessor of Pfizer, Inc. (“Pfizer”) subsidiary Pharmacia, and Upjohn Company LLC (hereinafter referred to as “Upjohn”) researched, tested, manufactured, marketed, and sold Provera.

The medical community became concerned regarding a possible connection between estrogens and breast cancer by 1976. In a June 14, 1976 internal memo, Wyeth physicians reported valid concern regarding the use of exogenous estrogen's role in increasing the incidence of breast cancer, but ultimately concluded that the use did not appear to do so. When informed that study findings indicating that estrogens might be a risk factor for breast cancer, possibly doubling the risk for women taking HRT for fifteen years or more, would be published in the *New England Journal of Medicine*, Wyeth circulated internal correspondence stating that it was crucial to formulate a plan "to either forestall or mitigate the possible adverse effects" of the study, and indicating concern that the study might impact Premarin's labeling requirements. Although a case-control study was considered, no such study was conducted.

Between the late 1980s and the early 1990s, additional studies linked HRT to an increased risk of breast cancer. Upjohn also was aware of the growing evidence indicating that HRT increased the risk of breast cancer, but did not pursue any studies to determine whether it did. A confidential Wyeth memorandum dated June 2, 1995, which was proposed to counter the publication of results of a recent Nurses' Health Study indicating that HRT caused breast cancer and increased mortality, stated: "Our recommended strategies are: Undermine/cast doubt on validity of data by raising concerns, via credible third party, regarding such issues as: inclusion criteria (e.g., exclusion of alcoholic beverage consumers). . .issue of statistical power . . . communicate estrogen's benefits in osteoporosis, heart disease[.]"

Between 1991 and 1996, Premarin's label and patient information sheet stated, "[t]he majority of studies have shown no association with the usual doses used for estrogen replacement therapy and breast cancer. Some studies have suggested a possible increased incidence of breast

cancer in those women taking estrogens for prolonged periods of time and especially if higher doses are used."

In 1997, Premarin's warning included the following language:

> Estrogens can cause development of other tumors in animals, such as tumors of the breast, cervix, vagina, or liver, when given for a long time. At present there is no good evidence that women using estrogen in menopause have an increased risk of such tumors, but there is no way yet to be sure they do not; and one study raises the possibility that use of estrogens in the menopause may increase the risk of breast cancer many years later.

Prempro's label in 1997 stated:

> Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy. The effect of added progestrins on the risk of breast cancer is unknown, although a moderately increased risk in those taking combined estrogen/progestin therapy has been reported. Other studies have not shown this relationship.

Premphase's 1998 label contained similar language, as did Premarin's and Prempro's 1999 labels. The HRT drugs' labels now carry a "black box"[3] warning for breast cancer.

In 1991, the National Institute of Health's ("NIH") Women's Health Initiative Study ("WHI") was initiated, and one of its study components proposed to evaluate the use of estrogen and progestin in postmenopausal women. However, on July 9, 2002, the National Heart, Lung and Blood Institute, a division of the NIH, announced it was terminating the estrogen plus progestin study component due to an unacceptably high incidence of invasive breast cancer among the participants. The initial results of this study were published in the *Journal of the American Medical Association* in July 2002, and included the conclusion that the overall health

[3]A "black box" warning, advising health professionals of the risks and precautions associated with a prescription drug, is the most serious type of warning required by the FDA in prescription drug labeling.

risks exceeded cardiovascular benefits from use of combined estrogen plus progestin for an average 5.2 year follow-up among healthy postmenopausal women.

Prior to starting HRT, Plaintiff Doliska Hanrahan (hereafter, the singular designation of "Plaintiff" shall refer to Doliska Hanrahan only) suffered from hot flashes, vaginal dryness, and mood swings. Plaintiff would experience three or four hot flashes daily.

Between 1991 and February 1997, several physicians, including Dr. John Applebaum, Dr. Deborah Parks, and Dr. Bruce Bryan, prescribed Premarin and Provera for Plaintiff. Initially, Plaintiff's gynecologist, Dr. Applebaum, prescribed Premarin and Provera for Plaintiff. Plaintiff's primary care physician, rheumatologist Dr. Parks, prescribed MPA for Plaintiff between January 1995 and February 1997. In February of 1997, Dr. Parks switched Plaintiff from Premarin and Provera to Prempro. Between February 1997 and September 1999, Dr. Parks and Plaintiff's gynecologist, Dr. Bryan, prescribed Prempro for her.

Dr. Bryan testified in a deposition that the increased risk of breast cancer was not known when he was treating Plaintiff with HRT, so "that's not something that I would have told her about." Although Plaintiff's physicians continue to prescribe HRT drugs, they changed their HRT prescribing practices and patient counseling in varying degrees after the results of the WHI study were published.

On September 16, 1999, Plaintiff was diagnosed with invasive ductal carcinoma of the right breast, and pathology staining revealed that the cancer was strongly positive for estrogen receptors and progesterone receptors. Thereafter, Plaintiff underwent surgery, radiation, chemotherapy, and adjuvant anti-hormonal medication therapy; and she required additional treatment for lymphedema following her cancer treatment.

II. PROCEDURAL BACKGROUND

On or about September 15, 2004, Plaintiffs filed a complaint against Defendants Wyeth; Upjohn a/k/a Pharmacia & Upjohn, Inc.; and Pfizer for personal injury caused by Defendants' prescription HRT [ECF No. 1].

Plaintiffs' action was subsequently transferred to by the Judicial Panel on Multidistrict Litigation (JPML) to the HRT multidistrict litigation (MDL) proceeding (*In Re: Prempro Products Liability Litigation*) pending in the Eastern District of Arkansas before the Honorable William R. Wilson, Jr. [ECF No. 9]. In January of 2011, the MDL court advised the JPML that coordinated or consolidated pretrial proceedings in Plaintiffs' action had been completed, and that remand to this Court was appropriate [ECF Nos. 12, 13, 14].

Thereafter, Plaintiff filed an amended complaint containing fourteen claims[4] [ECF No. 27]. Defendants filed their answers to Plaintiff's amended complaint, asserting several affirmative defenses, including the application of comment k of § 402A of the Restatement (Second) of Torts [ECF Nos. 30, 31]. Subsequently, Defendants filed their summary judgment motion, as well as several Motions to Exclude Testimony of Plaintiff's Experts, with memoranda in support of their motions [ECF Nos. 58-67].

III. SUMMARY JUDGMENT STANDARD

Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for summary judgment only if all of the information before the court shows "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." Fed. R.

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[4]The Court notes that Plaintiff's amended complaint does not contain claims denominated as Counts XIII or XIV. Instead, the amended complaint mistakenly denominates the two claims following Count XII as Count XV and Count XVI. For purposes of clarity, the Court shall refer to Plaintiffs' remaining claims as they are denominated in their amended complaint; hence, this discussion addresses Counts I-XII, XV, and XVI.

Civ. P. 56(c). *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The United States Supreme Court has noted that "summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the federal rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Id.* at 327 (quoting Fed. R. Civ. P. 1). "By its terms, [Rule 56(c)(1)] provides that the mere existence of ***some*** alleged factual dispute between the parties will not defeat an otherwise properly supported motion for judgment; the requirement is that there be no ***genuine*** issue of ***material*** fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Material facts are those "that might affect the outcome of the suit under the governing law," and a genuine material fact is one such that "a reasonable jury could return a verdict for the nonmoving party." *Id.* Further, if the non-moving party has failed to "make a showing sufficient to establish the existence of an element essential to that party's case, . . . there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 322-23.

The initial burden of proof in a motion for summary judgment is placed on the moving party to establish the non-existence of any genuine issue of fact that is material to a judgment in its favor. *City of Mt. Pleasant, Iowa v. Assoc'd Elec. Co-op., Inc.*, 838 F.2d 268, 273 (8th Cir. 1988). Once this burden is discharged, if the record does in fact bear out that no genuine dispute exists, the burden then shifts to the non-moving party who must set forth affirmative evidence and specific facts showing there is a genuine dispute on that issue. *Anderson*, 477 U.S. at 249. When the burden shifts, the non-moving party may not rest on the allegations in its pleadings, but by affidavit and other evidence must set forth specific facts showing that a genuine issue of

material fact exists. Fed. R. Civ. P. 56(e). To meet its burden, the non-moving party may not rest on the pleadings alone and must "do more than simply show there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In fact, the non-moving party must show there is sufficient evidence favoring the non-moving party that would enable a jury to return a verdict for it. *Anderson*, 477 U.S. at 249; *Celotex*, 477 U.S. at 324. "If the non-moving party fails to produce such evidence, summary judgment is proper." *Olson v. Pennzoil Co.*, 943 F.2d 881, 883 (8th Cir. 1991).

IV. ANALYSIS

Defendants present many arguments in their Motion, some which are applicable to all defendants, but others that pertain only to Defendant Pfizer. In their Motion, Defendants assert that all of Plaintiff's claims against Pfizer fail because Plaintiff cannot prove that she ingested a product manufactured or sold by Pfizer, and because there is "no basis in fact or law to impose liability on Pfizer based on Plaintiff's use of Wyeth's Premarin and Prempro or Upjohn's Provera." The Court will analyze Pfizer's asserted ground for summary judgment before turning to the arguments pertinent to all Defendants.

Defendants maintain that Pfizer is not liable to Plaintiff, asserting that there is no "causal connection" or "causal relationship" between Pfizer and Plaintiff's injuries, and stating that it is "indisputable that Pfizer neither manufactured nor sold Provera, Premarin, MPA, or Prempro during the time of Plaintiff's alleged use." Plaintiff argues, however, that the record demonstrates a genuine issue of fact as to whether Pfizer can be held liable for the debts and liabilities of Wyeth or Upjohn under the doctrine of successor liability (Counts XV and XVI of the amended complaint) due to Pfizer's purchase of Wyeth's and Upjohn's assets.

In its January 13, 2011 Amended MDL Pretrial Order for Remanded Cases and Second Suggestion of Remand designating this case and other cases as ripe for remand, the MDL court stated that the cases "should involve only allegations of breast cancer injury against only Defendants Wyeth and Upjohn." *In re Prempro Prods. Liability Litig.*, No. 03-1507, 2011 WL 124188 at *5 (E.D. Ark. Jan. 13, 2011). The MDL court expressly designated this Pretrial Order, along with any supplements and amendments, as the Final Pretrial Order pertaining to the listed cases. *Id.* at *1. In previous orders concerning its dismissal of Pfizer as a defendant in the Prempro Products Liability Litigation, the MDL Court denied motions to alter, amend, vacate, or reconsider its dismissal order, stating, among other things, that Pfizer's acquisition of Wyeth would have no effect on the plaintiffs' claims against Wyeth because "even when or if the acquisition is completed, Pfizer will not be 'acquiring the assets or liabilities of Wyeth'" [ECF No. 61-14].

Generally, under the doctrine of the law of the case, orders issued by a federal transferee court remain binding when the case is remanded to the transferor court. *Winter v. Novartis Pharm. Corp.*, No. 06-04049, 2011 WL 5008008 at *2 (W.D. Mo. Oct. 20, 2011). The doctrine of the law of the case provides that, when a court decides a rule of law, its decision "should govern the same issues in subsequent stages in the same case." *Id.* Thus, the doctrine precludes relitigation of matters already determined, "protecting the expectations of the parties, ensuring uniformity of decisions and promoting judicial efficiency." *Unigroup, Inc. v. Winokur*, 45 F.3d 1208, 1211 (8th Cir. 1995). Although the doctrine is discretionary, allowing a court to depart from the law of the case if cogent or compelling reasons to do so are shown, courts are hesitant to disturb transferee court's rulings in MDL proceedings because "doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial

proceedings." *Winter*, 2011 WL 5008008 at *2 (citation omitted); *Unigroup*, 45 F.3d at 1211. Reasons warranting departure from the doctrine include a subsequent change in law, the availability of new evidence, or the need to correct a clear error or to prevent manifest injustice. *Duetsch v. Novartis Pharm. Corp.*, 768 F. Supp.2d 420, 428 (E.D.N.Y. 2011).

Plaintiff argues that the record demonstrates a geniune issue of fact as to whether Pfzier can be held liable for the debts and liabilities of Wyeth under the theories of express or implicit assumption of debts or liabilities, de facto merger, and continuation. Plaintiff's arguments do not provide compelling grounds to disturb the MDL ruling in the transferee court's Final Pretrial Order. The Court therefore concludes that Defendant Pfizer is entitled to summary judgment on Counts II, IV, VI and XVI of Plaintiff's Amended Complaint based on the law of the case, because Plaintiff cannot prove that she ingested a product manufactured or sold by Pfizer. Consequently, as Plaintiff has no factual or legal basis for imposing liability against Pfizer based on her use of Wyeth's or Upjohn's HRT drugs, Pfizer must be dismissed as a defendant in this action.

In her Response in Opposition to Defendants' Motion for Summary Judgment [ECF No. 74, p. 5, n. 11], Plaintiff withdrew claims for fraud, breach of express warranty, and breach of implied warranty (denominated as Counts VII, VIII, IX, X, XI, and XII in the amended complaint). Consequently, Defendants' motion is denied as moot as to those claims, and the Court limits its discussion to the remaining counts, denominated in the complaint as Counts I-VI, XV, and XVI: Count I, negligence (against Wyeth); Count II, negligence (against MPA Defendants Pfizer and Upjohn); Count III, Strict Product Liability (against Wyeth); Count IV, Strict Product Liability (against Pfizer and Upjohn); Count V, Strict Product Liability - Failure to Warn (against Wyeth); Count VI, Strict Product Liability - Failure to Warn (against Pfizer and

Upjohn); Count XV, Joint Ventures, Parent/Subsidiaries, and/or Successor Corporation Liability (against Wyeth); and Count XVI, Joint Ventures, Parent/Subsidiaries, and/or Successor Corporation Liability (against Pfizer and Upjohn).

In their remaining common grounds, Defendants argue that summary judgment should be entered in their favor on Plaintiff's negligence and strict liability failure-to-warn claims (Counts I, II, V and VI) because Plaintiff has no evidence that Defendants' warnings were inadequate or that their alleged failure to warn caused her injuries. Defendants further aver that summary judgment is appropriate on Plaintiff's negligent preparation, research, development, inspection, labeling, marketing, promotion and selling claims (Counts I and II) because such claims are not recognized causes of action under Missouri law. They argue that Plaintiff's claims for negligent design and strict products liability (Counts I, II, III, and IV) fail because they have not alleged any specific defect in the design of Defendants' products and because Missouri courts have adopted comment k[5] to Section 402A of the Restatement (Second) of Torts. Defendants also

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[5]comment k to Section 402A of the Restatement (Second) of Torts provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently

challenge any claim for manufacturing defect; however, Plaintiff specifically states she is not pressing any claim for manufacturing defect (*see Defendants' Motion* at 22; *Plaintiff's Response* at 30). Consequently, Defendants' argument on this point is moot.

A. The Record Presents a Genuine Issue of Material Fact as to Whether Defendants' Warnings Were Inadequate and as to Whether the Alleged Failure to Warn Caused Plaintiff's Injuries

Defendants argue that summary judgment should be entered in their favor on Plaintiff's negligence and strict liability failure-to-warn claims (Counts I, II, V and VI) because Plaintiff has no evidence that Defendants' warnings were inadequate or that Defendants' alleged failure to warn caused their injuries.

To prevail on a negligent failure-to-warn claim, Plaintiff must prove that Defendants manufactured or designed the HRT drug; that the HRT drug did not contain an adequate warning of its alleged defect or hazard; that Defendants failed to use ordinary care to warn of the risk of harm from the alleged defect or hazard; and that, as result of such failure, Plaintiff sustained damage. *Moore v. Ford Motor Co.*, 332 S.W3d 749, 764 (Mo. 2011).

To recover under the theory of strict failure-to-warn liability, Plaintiff must prove that the HRT drug was unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics; that Defendants did not give an adequate warning of the danger; that the product was used in a manner reasonably anticipated; and that Plaintiff was damaged as a direct result of the HRT drug being sold without an adequate warning. *Pollard v. Ashby*, 793 S.W.2d 394, 397-98 (Mo. App. E.D. 1990). Admissible expert testimony that additional or other warnings might have altered the plaintiff's behavior is required in failure-to-warn cases. *See*

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reasonable risk.

Bryant v. Laiko Int'l Co., Inc., No. 05-00161, 2006 WL 2788520 at ** 9-10 (E.D. Mo. Sept. 26, 2006); *Davidson v. Besser Co.*, 70 F. Supp.2d 1020, 1023 (E.D. Mo. 1999).

In the memorandum submitted in support of their Motion, Defendants claim that summary judgment in their favor on Plaintiff's negligence and strict liability failure-to-warn claims is appropriate because Plaintiff has no admissible evidence from an expert-of-fact witness regarding the adequacy of the warnings Defendants placed on Premarin, Provera, and Prempro.

Defendants acknowledge that Plaintiff has designated several experts, including Dr. Cheryl Blume and Dr. Suzanne Parisian[6], to testify regarding the adequacy of Defendants' warnings. Nevertheless, Defendants maintain that the opinions of these experts are "inherently unreliable and are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1995)." In making their argument, Defendants incorporate by reference a Motion to Exclude the testimony of these experts and their supporting memorandum, which Defendants filed concurrently with their summary judgment motion [ECF Nos. 66, 67].

Rule 702 mandates a policy of liberal admissibility, and expert testimony is permitted if it will assist the trier of fact in understanding the evidence or to determine a fact in issue. Fed. R. Evid. 702; *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). To be admitted

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[6]Defendants also challenge the admissibility of testimony by Dr. Donald F. Austin regarding a claim that Defendants failed to adequately test their HRT products prior to marketing them. Plaintiff indicates that she does not intend to elicit testimony from Dr. Austin regarding the inadequacy of Defendants' warnings. Rather, Plaintiff states that Dr. Austin will opine on the types of testing and study available to pharmaceutical companies during the relevant time. Consequently, Defendants' motion is moot as to Dr. Austin on the warning adequacy issue. The Court further notes that, although Defendants' Motion to Exclude requests the Court to exclude the testimony of Dr. Bruce Patsner also, their Motion for Summary Judgment and supporting memorandum do not include argument addressing this expert, or challenging the admissibility of his testimony.

under Rule 702, proposed expert testimony must meet three prerequisites: 1) any evidence based on scientific, technical or other specialized knowledge must be useful to the fact finder in determining a fact in issue; 2) the proposed witness must be qualified to assist the fact finder; and 3) the proposed evidence must be reliable or trustworthy in an evidentiary sense. *Id.; Daubert*, 509 U.S. at 590-93.

As to the qualifications of the proposed witnesses to assist the finder of fact in this matter, the Court notes that Dr. Parisian is a medical doctor and a former Chief Medical Officer at the Food and Drug Administration ("FDA").[7] Dr. Blume, president of a consulting firm specializing in pharmaceutical development and registration activities, has a doctoral degree in pharmacology and toxicology, and enjoyed a long career as a pharmaceutical company executive whose responsibilities included overseeing preclinical and clinical programs associated with pharmaceutical product development, securing FDA approval of prescription drugs and revising drug labels as needed.

Concerning the usefulness of the proposed evidence, Plaintiff states that Dr. Parisian and Dr. Blume will testify regarding the inaccuracy and inadequacy of Defendants' product labeling. She further asserts that the testimony of Dr. Parisian and Dr. Blume will be used to "explain complex, technical subjects to the jury, including the process of drug development, the procedures involved in FDA approval, the limitations on FDA review of drug applications and post approval activities and, significantly, the meaning of specialized terminology appearing in Defendants' documents." Given the nature of the proceeding and the issues presented, the Court

[7]*See Daniel v. Wyeth Pharm., Inc.*, 15 A.3d 909, 926 (Pa. 2011); *Kendall v. Wyeth, Inc.*; Nos. 936-2010, 937-2010, 1154-2020; 2012 WL 112609 at **5-6 (Pa. Super. Jan. 3, 2012).

finds both proffered expert witnesses to be qualified to assist the finder of fact regarding the adequacy of the defendants' product labeling.

Defendants argue that the opinions of these experts regarding the adequacy of the label warnings are unreliable because the opinions are not based on a reliable methodology or any objective standard of care. A district court's goal in assessing expert testimony is to ensure that "all scientific testimony is both reliable and relevant." *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010) (quoting *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006)). The reliability requirement means that "the party offering the expert testimony must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid," while the relevance requirement demands "the proponent must show that the expert's reasoning or methodology was applied properly to the facts at issue." *Id.* (internal quotations and citations omitted).

Rule 702's requirements notwithstanding, "[c]ourts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Marmo*, 457 F.3d at 758. This is because the Rule "only requires that an expert possess 'knowledge, skill, experience, training, or education' sufficient to 'assist' the trier of fact, which is 'satisfied where expert testimony advances the trier of fact's understanding to any degree.'" *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal citation omitted). As such, "[g]aps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Id.* at 1100-01. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1995).

Defendants' Motion to Exclude as to these two experts and their proposed testimony regarding the adequacy of Defendants' warnings will be denied. These witnesses have specialized knowledge of the regulatory procedures, pharmaceutical labeling, FDA standards and practice, governmental statutes and regulations, pharmaceutical industry customs and practices, administrative rules, internal policies, and other factors that can assist the trier of fact in determining the adequacy of Defendants' label warnings. Defendants' challenge to the testimony of these experts goes more to the weight, rather than the admissibility, of the evidence.

Although Defendants' summary judgment motion does not challenge the qualifications of Dr. Donald F. Austin, MD, or Bruce Patsner, MD, on this point, Defendants' Motion to Exclude does request that the testimony of these two experts be excluded, Dr. Patsner's in its entirety, and Dr. Austin's to the extent it concerns Defendants' alleged failure to test their HRT products. In the interest of judicial efficiency and economy, the Court shall address Defendants' *Daubert* challenge regarding these two experts.

Concerning Dr. Austin, Defendants appear to concede that he is qualified, as an epidemiologist, to interpret epidemiologic research and state opinions about the relationship between HRT and breast cancer. However, as stated above, Defendants do challenge the admissibility of his opinions concerning any failure to test by Defendants. In response, Plaintiff states that she does not intend to elicit any testimony from Dr. Austin regarding whether Defendants failed to test, failed to warn, or acted unreasonably. Rather, Plaintiff indicates that Dr. Austin will opine as to the types of testing and studying that were available to a pharmaceutical company during the relevant time frame. As Defendants do not challenge the propriety of such testimony, Defendants' motion will be denied as moot as it concerns Dr. Austin.

As to Dr. Patsner, Defendants argue in their Motion to Exclude that his failure-to-warn opinion is inadmissible because it is not based on a reliable methodology. Dr. Patsner, currently a health law and bioethics professor, is a retired gynecologic oncology physician and a former FDA medical officer. The Court finds that, like Drs. Parisian and Blume, Dr. Patsner is qualified, based on his training and experience, to testify with respect to adequacy of Defendants' product labeling, and that he has specialized knowledge that can assist the trier of fact in determining the reasonableness of a pharmaceutical company's conduct. Defendants' Motion to Exclude Opinions of Plaintiff's Experts Drs. Parisian, Blume, Austin and Patsner [ECF No. 66] will be denied.

Accordingly, the record contains admissible expert testimony regarding the warnings Defendants placed on their pharmaceutical products, and the Court finds that it presents a genuine issue of material fact as to whether the Defendants' warnings were inadequate.

Defendants further argue that, under the learned intermediary doctrine, no alleged failure to warn by Defendants could have been the proximate cause of Plaintiff's injuries. Defendants claim that the record clearly establishes that Plaintiff's prescribing physicians were fully aware of the risk of breast cancer associated with HRT when they prescribed those medications for her, and Defendants argue that, due to her physicians' awareness, no alleged failure to warn by Defendants could have been the proximate cause of Plaintiff's injury. Defendants further aver that Plaintiff cannot establish that an adequate warning would have altered her physicians' decisions to prescribe the medications. Consequently, Defendants assert that Plaintiff has no evidence that Defendants' alleged failure to warn caused Plaintiff's injuries.

It is incumbent upon drug manufacturers to provide physicians with adequate warnings of the risks associated with their prescription products. *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d

404, 419-420 (Mo. App. E.D. 1999). A corollary to this rule is the learned intermediary doctrine, which recognizes the role of a physician as a "learned intermediary" between a drug manufacturer and a patient, and provides that a manufacturer's failure to provide a prescribing physician with an adequate warning is not the proximate cause of a patient's injury, if the prescriber had independent knowledge of the risk an adequate warning would have communicated. *Id*. at 420.

The Court concludes that the record demonstrates a genuine issue of fact as to whether Plaintiff's physicians fully knew of the breast cancer risk posed by the HRT medication regimen they prescribed for her. One of Plaintiff's prescribers testified that he "certainly didn't have any idea that there would be a – I mean, it was a big surprise to hear that it was – that estrogen and progesterone together could cause an increase in breast cancer." [ECF No. 74-1, at 115-116]. Another physician who prescribed Plaintiff's HRT medications testified, "I remember that in the timeframe of when [Plaintiff] was being treated in the . . . mid to late 90's, that there was evidence that treatment of healthy women with hormones was protective for their cardiovascular health, and that it was thought to be in their interest of their longevity to give them [HRT] to prevent heart disease, and that there was not a concern about [HRT] causing breast cancer." [ECF 74-2, at 30]. Another one of Plaintiff's prescribers testified that, after results of the WHI study were released, her counseling regarding HRT and the risk of breast cancer changed, as did her prescribing approach [ECF No. 74-2, at 254-260].

Defendants further argue that Plaintiff cannot establish that a different warning would have altered the decisions of Plaintiff's physicians to prescribe HRT medication for her. However, Missouri aids plaintiffs in proving that a warning would have altered the behavior of their prescribing physicians by presuming that a warning will be heeded. *Arnold v. Ingersoll-*

Rand Co., 834 S.W.2d 192, 194 (Mo. banc 1992). There is a rebuttable presumption that arises as a matter of law. *Grady v. Am. Optical Corp.*, 702 S.W.2d 911, 918 (Mo. App. E.D. 1985). Moreover, the record contains evidence indicating that Plaintiff's doctors did alter their prescribing practices after the results of the WHI study were published indicating increased breast cancer risk with HRT. Having found no compelling evidence submitted by Defendants establishing that Plaintiff's prescribing physicians would not have heeded an adequate warning, the Court concludes that the causation issue is a question for the finder of fact. Thus, Defendants have not established a right to judgment on this issue.

B. Summary judgment is not appropriate as to the claims contained in Counts I and II because Missouri recognizes causes of action alleged in these counts.

Defendants argue that Plaintiff's negligence claims should be dismissed as a matter of law, stating that they fail as a matter of law because Missouri does not recognize causes of action for claims contained in Counts I and II of Plaintiffs' complaint. Defendants aver that Counts I and II assert causes of action for: 1) negligent marketing, promotion and sale; 2) negligent testing, research and development; and 3) negligent manufacturing. The Court need not address Defendant's argument concerning any negligent manufacturing claim, because Plaintiff specifically states in her Response that she is "not pressing any claim for manufacturing defects, so Defendants' argument on that point is moot."

Concerning Defendants' challenge to Counts I and II on the basis that these counts assert causes of action that Missouri does not recognize, the Court finds that Counts I and II sufficiently state negligent failure-to-warn claims, and that Plaintiff's marketing and testing allegations are aspects of her failure-to-warn claims. *See Moore*, 332 S.W.3d at 764 (stating elements of failure-to-warn claim based in negligence). As negligent failure to warn is a cause of action recognized by Missouri courts, the Court concludes that Plaintiff's negligence claims should not be

dismissed as a matter of law. Further, the Court holds summary judgment is not appropriate as to Counts I or II of Plaintiff's complaint on the basis urged by Defendants.

C. Plaintiff's Claims for Negligent Design and Strict Liability (Counts I, II, III and IV) Do Not Fail Due to any Lack of Proof of a Design Defect, and Comment k to Section 402A of Restatement (Second) of Torts Does Not Preclude Plaintiff's Strict Liability Claims

Defendants assert that Plaintiff's design defect claims should be dismissed as a matter of law, and that Plaintiff's causes of action for negligent and strict liability fail because Plaintiff cannot prove a defect in the design of Premarin, Provera, or Prempro.

Because design defect and failure-to-warn theories are distinct theories protecting consumers from dangers that arise in different ways, a finding of a product defect is not a necessary predicate to a failure-to-warn action. *Moore*, 332 S.W.3d at 756. The Court's determination that Counts I and II of Plaintiff's complaint sufficiently state negligent failure-to-warn claims precludes dismissal of these counts as a matter of law.

However, Counts III and IV of Plaintiff's complaint do assert strict product liability claims against Defendants, alleging that the HRT drugs "were defective in design or formulation in that, when they left the hands of [Defendants], the foreseeable risks exceeded the benefits associated with the design or formulation." [ECF No. 27, at 30]. Plaintiff alternatively alleges that the design or formulation of the drugs were defective, "in that when they left the hands of [Defendants], they were unreasonably dangerous and more dangerous than an ordinary consumer would expect." [ECF No. 27, at 30]. Plaintiff further alleges that the drugs were defective "due to inadequate warning and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of it." [ECF No. 27, at 31].

Defendants argue that Plaintiff's design defect claims should be dismissed as a matter of law because Plaintiff cannot prove a defect specific to the design of the HRT drugs, and because

comment k to Section 402A of the Restatement (Second) of Torts prohibits Plaintiff's strict liability design defect claim.

Section 402A states the strict-liability rule for sellers of products that cause physical harm to their users or consumers, imposing liability on sellers of "any product in a defective condition unreasonably dangerous" where the seller is engaged in the business of selling the product and the product is expected to and does reach the user or consumer substantially unchanged from its original condition when sold. Restatement (2d) Torts § 402A. The terminology of the Restatement's language indicates that a product's defect need not be "a matter of errors in manufacture," and that the product is defective "*when it is not accompanied by adequate instructions and warning of the dangers attending its use*." *Hill v. Searle Lab.*, 884 F.2d 1064, 1067 (8th. Cir. 1989) (italics in original). Here, Plaintiff's proposed evidence includes admissible expert testimony supporting her allegations that the HRT drugs were defective due to inadequate warning, clinical trials, testing, study, and reporting. The Court finds that Plaintiff has offered sufficient evidence to support a finding that Defendants' HRT drugs were in a defective condition unreasonably dangerous when they reached Plaintiff. Thus, Plaintiff's design defect claims do not fail due to lack of proof of a design defect.

Nevertheless, comment K to Section 402A of the Restatement (Second) of Torts does provide manufacturers of prescription products with an exception to strict liability upon a showing that the products fall within its scope. Accordingly, the Court must determine whether the evidence shows that comment K applies to Defendants' HRT prescription products.

Comment k to Section 402A of the Restatement (Second) of Torts addresses the application of strict liability to unavoidably unsafe products such as prescription medication, imposing liability on a drug manufacturer only if it failed to warn of dangerous propensities that

it either knew or should have known. *Pollard*, 793 S.W.2d at 398-99; ***see also Restatement (Second) Torts § 402A, comment k*** ("[t]he seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use"). Missouri courts have determined that the comment's terms indicate comment k does not apply to cases involving manufacturing defects or inadequate warnings. *Pollard*, 793 S.W.2d at 400. Therefore, although comment k would not apply to the strict liability failure-to-warn claims contained in Counts V and VI of Plaintiff's complaint, it could provide Defendants with an exception to strict liability as to the claims alleged in Counts III and IV, upon a showing that the HRT products fall within the comment's scope.

In cases where a design defect is alleged, Missouri courts have limited the application of comment k to "drugs shown to be incapable of being made safe given the present state of human knowledge but which have such a high degree of social need that their use is warranted, so long as there are sufficient warnings." *Id*. at 399-400.

The application of comment k is an affirmative defense. *Id*. at 400. Thus, the manufacturer bears the burden of establishing that a drug falls within the realm of comment k protection. *Id*. To meet this burden, the manufacturer must establish two requirements. *Id.* First, the manufacturer must show that the drug's risk is unavoidable, "by demonstrating that, given the current state of knowledge, no feasible alternative design exists that would accomplish the same purpose with a lesser risk." *Id*. Next, the manufacturer must demonstrate that the drug's overall benefits outweigh the risks it presents to individual safety. *Id*. This prong is a balancing test, with the weighing performed at the time the product was distributed to the plaintiff. *Id*.

Although Defendants raised comment K as an affirmative defense in their answer, they have not established either of the comment's requirements. Defendants' summary judgment argument regarding this affirmative defense begins by stating that Plaintiff cannot establish that their products are unreasonably dangerous because comment K specifically recognizes that prescription drugs such as their HRT products are not unreasonably dangerous. Defendants then state that comment K expressly recognizes that imposing strict liability on manufacturers of "unavoidably unsafe" products such as their HRT drugs is improper. Without any further discussion or analysis, Defendants state, in a conclusory manner, that comment k applies to this case because "the products at issue are incapable of being rendered non-dangerous but provide benefits to society that outweigh their attendant risks." Defendants have not offered or directed the Court's attention to evidence showing that their HRT products are unavoidably unsafe, nor to evidence establishing their drugs' societal benefits. The Court finds that Defendants have not met their burden of establishing that comment k excludes their HRT products from strict liability; thus, summary judgment in their favor is not appropriate on this asserted basis.

2. Plaintiff's Failure-to-Warn Claims Are Not Barred by the Learned Intermediary Doctrine

Manufacturers of prescription drugs have a duty to warn physicians properly of the risks involved with a prescription product, and "it is incumbent upon the manufacturer to bring the warning home to the doctor." *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d at 419.

A corollary to this rule is the "learned intermediary doctrine," which deems any warning given to a physician as being a warning to his patient *Id.* Under this doctrine, the failure of a drug manufacturer to provide a physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of his patient's injury if the prescribing physician

had independent knowledge of the risk that should have been communicated. *Id.* at 420. However, Missouri courts have adopted a "heeding presumption," which assumes that doctors will perform non-negligently when presented with an adequate warning; consequently, in the absence of compelling evidence establishing that the absence of a warning did not cause the injury, the causation question becomes one for the jury. *Moore*, 332 S.W.3d at 762-63; *Grady*, 702 S.W.2d at 918.

Although conflicting, the evidence on proximate causation is sufficient to survive summary judgment on Plaintiff's failure-to-warn claims. Plaintiff's prescribing physicians testified that they still prescribe estrogen plus progestin to menopausal women; however, noted, they also testified that they have changed their prescription practices since the results of the WHI study became commonly known. Consequently, Plaintiff produced sufficient evidence to preclude a grant of summary judgment on these claims.

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion to Exclude Testimony of Plaintiff's Experts [ECF No. 66] is **DENIED**.

IT IS FURTHERED ORDERED that Defendants' Motion for Summary Judgment [ECF No. 60] is **GRANTED, in part, and DENIED, in part**. Defendants' Motion for Summary Judgment is **GRANTED**, as to Defendant Pfizer only, on Counts II, IV, VI and XV of Plaintiff's Amended Complaint. **IT IS FURTHER ORDERED** that Defendant Pfizer is hereby **DISMISSED** as a defendant in this matter.

IT IS FURTHER ORDERED that, as to all defendants except Pfizer, Defendants'

Motion for Summary Judgment is **DENIED** as to Counts I, II, III, IV, V, VI, XV and XVI.

Dated this 25th day of June, 2012.

E. RICHARD WEBBER
SENIOR UNITED STATES DISTRICT JUDGE